Medigus leading the GERD revolution

MAR 19 2014

510(k) Summary

Medigus SRS Endoscopic Stapling System

Criteria	*Information*
510(k) Owner	Medigus Ltd. Building 7A Omer Industrial Park Omer, 84965 Israel Phone: +972-8-6466880 Fax: +972-8-6466770
Date Prepared	March 18, 2014
Contact Person	Sheila Stevens, PhD US Clinical and Regulatory Affairs
Device Name	Medigus SRS Endoscopic Stapling System
Trade Name/ Proprietary Name	Medigus Ultrasonic Surgical Endostapler (MUSE)
Common Name	Endostapler, endoscopic stapler
Classification Name	Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (GERD) 21 CFR 876.1500- Endoscope and Accessories; Class II; Product code: ODE
Predicate Device	K120299 Medigus SRS Endoscopic Stapling System
Intended Use/ Indications for Use	The SRS Endoscopic Stapling System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.

Device Description

The Medigus SRS is an Endoscopic Surgical Stapling System. The system enables the operator to staple the fundus of the stomach to the esophagus, in 2 or more locations around the esophageal circumference, entirely through the mouth, without any incisions. The system consists of three main parts: the endoscopic stapler, the control console and several accessories.

The endoscopic stapler is a single use, sterile device which resembles an endoscope in appearance and material construction. The distal tip of the device contains a video camera, ultrasonic range finding sight, illumination, irrigation port, insufflation port, and the staple anvil.

The distal tip is retroflexed to align with the staple cartridge located in the shaft of the stapler. An alignment pin in the distal tip is used for initial positioning of the anvil against the cartridge. The cartridge is provided sterile and contains standard, 4.8 mm titanium surgical staples. Each application of the device fires five staples in 3 staggered rows. A new cartridge is loaded for each application.

The control console includes the insufflation, light and camera electronics.

The associated accessories include:

- Irrigation bottle with liquids for irrigation of the camera lens
- Silicon tubes for connecting the console and other accessories to the stapler
- Standard overtube for protecting patient's pharynx
- Tweezers to remove and replace staple cartridge
- Staple cartridges

Differences between the predicate device and subject device are summarized as follows:

- The subject device has a single console whereas the predicate had two consoles.
- The subject device has an improved user interface and software controls compared to the predicate.
- The subject device uses an electric motor to power staple ejection, whereas the predicate device manually ejected staples.
- The subject device contains an alignment pin mechanism to allow accurate alignment of the stapling anvil and cartridge.
- The subject devices uses an LED for illumination, whereas the predicate contained a Xenon lamp.
- The subject device contains a CMOS camera, whereas the predicate contained a CCD camera.

Performance Data

The following non-clinical performance data was provided in support of the substantial equivalence determination:

- Biocompatibility testing
- Electrical safety and electromagnetic compatibility
- Software validation
- Sterilization validation
- Mechanical and acoustic testing
- LED photobiological and thermal safety testing
- Camera/optics characterization testing

Substantial Equivalence

The Medigus SRS Endoscopic Stapling System has the same intended use and indications and similar principles of operation, and technological characteristics as the cleared, predicate version of the device. The minor differences in the subject device's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the subject device is as safe and effective as the predicate SRS Endoscopic Stapling System. Thus, the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

Medigus, Ltd.
Sheila S. Stevens, Ph.D.
US Regulatory and Clinical Affairs
2121 North California Blvd., Suite 290
Walnut Creek, CA 94596

Re: K132151
Trade/Device Name: SRS Endoscopic Stapling System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: March 13, 2014
Received: March 18, 2014

Dear Sheila S. Stevens,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 13

Indications for Use Statement

510(k) Number (if known): K132151

Device Name:

SRS Endoscopic Stapling System

Indications for Use:

The SRS Endoscopic Stapling System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801 Subpart D) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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